RESULTS OF INVESTIGATION: Examination indicated that the article was a canister-type vacuum cleaner equipped with various attachments, including a water reservoir.

LIBELED: 8–30–61, N. Dist. Ga.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use for the prevention of infectious and parasitic diseases such as tuberculosis, meningitis, influenza, tonsillitis, erysipelas, and osteomyelitis, cancer, colds, and infections due to staphylococcus and streptococcus germs which were the diseases, conditions, and purposes for which the article was offered in oral statements made by Bill Hammond, salesman for Rexair Advertising of Atlanta, Inc., on or about July 27, 1961, at Decatur, Ga., in the presence of a Food and Drug Administration inspector.

DISPOSITION: On 11–27–61, Rexair Advertising of Atlanta, Inc., claimant, filed an intervention and claim to the article denying the allegations of misbranding of the libel and, without admitting that the article was misbranded while held for sale after shipment in interstate commerce, or was held illegally within the jurisdiction of the court, consented to the entry of a decree of condemnation, a decree of injunction, and a decree permitting the repossession and disposition of the article by the claimant under Government supervision.

On 12–6–61, a consent decree of condemnation and injunction was entered which permitted the repossession and bringing of the article into compliance with the law. The decree further enjoined the claimant and its officers, agents, employees, representatives, and all or any other person in active concert or participate with it or any of them from doing the following acts:

(a) Introducing into interstate commerce any "Rexair" cleaning device, any vacuum cleaning machine, or any other cleaning device, which is represented to be useful in the diagnosis, cure, mitigation, or prevention of infectious and parasitic diseases, tuberculosis, meningitis, influenza, tonsillitis, erysipelas, osteomyelitis, cancer, colds, staphylococcus and streptococcus infections, or any other disease or abnormal health condition of man;

(b) Doing any act with respect to the "Rexair" cleaning device, any vacuum cleaning machine or any other cleaning device, while such article is held for sale after shipment in interstate commerce, which will result directly or indirectly in said article being represented to be useful in the diagnosis, cure, mitigation, treatment, or prevention of infectious and parasitic diseases, tuberculosis, meningitis, influenza, tonsillitis, erysipelas, osteomyelitis, cancer, colds, staphylococcus and streptococcus infections, or any other disease or abnormal health condition of man.

DRUGS AND DEVICE ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS AND DEVICE FOR HUMAN USE*

6934. Liver-folic acid. (F.D.C. No. 46867. S. No. 31–394 T.)

QUANTITY: 10 individually ctnd. 10-cc. vials at Temple City, Calif.

SHIPPED: 10–1–61, from Philadelphia, Pa.

LABEL IN PART: (Vial and ctn.) "10 cc Multiple-Dose Vial Liver-Folic Acid Vitamin B–12 60 mcgm. (Crystalline) Folic Acid 5 mg. Lot No. 1469."

*See also No. 6907.

RESULTS OF INVESTIGATION: Analysis showed that the article contained about 50 percent of the declared amount of vitamin B_{12}.

LIBELED: 12–29–61, S. Dist. Calif.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it was purported to possess; and 502(a)—the label statement "Vit. B–12 60 mcgm." was false and misleading.

DISPOSITION: 1–25–62. Default—destruction.

6935. Liver injection (crude) and Liv-I-Plex injection. (F.D.C. No. 46612. S. Nos. 30–163/4 T.)

QUANTITY: 80 30-cc. vials of *liver injection (crude)* and 104 30-cc. vials of *Liv-I-Plex injection*, at Phoenix, Ariz.

SHIPPED: On 4–26–60 and 11–30–60, from Los Angeles, Calif., by Injectable Pharmacal Co.

LABEL IN PART: (Vial of liver injection) "Sterile Multiple Dose Vial Liver Injection (Crude) USP Each cc. contains Vitamin B_{12} activity equivalent to 2 micrograms of cyanocobalamin Rocky Mountain Pharmacal Co. Phoenix, Arizona Distributors"; (ctn. of Liv-I-Plex) "Sterile Multiple Dose Vial Liv-I-Plex Fortified Each 2 cc contains: Liver Injection USP 0.1 cc Folic Acid 2 mg. Iron Peptonized 59 mg. Pyridoxine H.C.L. 0.3 mg. Riboflavin 0.3 mg. Sodium Citrate 1% Niacinamide 50 mg. Phenol 0.5% Vitamin B_{12} Cryst. 30 mcgm. Procaine 1% Distributed by Rocky Mountain Pharmacal Co."; and (vial of Liv-I-Plex) "Sterile Multiple Dose Vial Liv-I-Plex Forte Each cc represents Vitamin B–12 activity (from liver injections, U.S.P. 10 mcgm. per cc) equivalent to: Cyanocobalamin 2 Mcgm. Vitamin B–12 (Crystalline, U.S.P.) 15 Mcgm. Peptonized Iron 20 Mg. Thiamine Hydrochloride, U.S.P. 10 Mg. Riboflavin, U.S.P. 0.5 Mg. Pyridoxine Hydrochloride 1.0 Mg. Panthenol 1.0 Mg. Niacinamide USP 10 Mg. Sodium Citrate, U.S.P. 1.0% Procaine Hydrochloride U.S.P. 0.5% Rocky Mountain Pharmacal Co."

RESULTS OF INVESTIGATION: Analysis showed that the article, *liver injection (crude)*, contained 225 percent of the declared potency of vitamin B_{12}. The National Formulary permits a variation in strength for *liver injection (crude)* up to 150 percent of the potency stated on the label.

The *Liv-I-Plex injection* was in a vial bearing a label which differed from the label on the carton.

LIBELED: 11–9–61, Dist. Ariz.; amended libel 12–1–61.

CHARGE: *Liver injection (crude)*, 501(b)—when shipped, the article purported to be *liver injection (crude)*, a drug, the name of which was recognized in the National Formulary, an official compendium, and its strength differed from the standard set forth in such compendium since, when assayed in accordance with the method prescribed in the National Formulary, the article contained 225 percent of the potency of its labeled amount of cyanocobalamin; 502(a)—the label statement "Each cc. vitamin B_{12} activity equivalent to 2 micrograms of cyanocobalamin" was false and misleading as applied to a product containing more than the labeled amount of vitamin B_{12}; and the label statement "Liver Injection (Crude) U.S.P." was false and misleading since the article was recognized in the National Formulary and not in the United States Pharmacopeia, as such label statement represented.

Liv-I-Plex injection, 502(a)—the vial label and the carton label bore statements concerning the composition of the article which were false and mislead-